Notice of Allowability	Application No. 09/424,527	Applicant(s) FARMER ET AL.	
	Examiner Aaron J. Kosar	Art Unit 1651	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to *the telephonic interview of 12/20/2007*.

2. ☒ The allowed claim(s) is/are *1,2,4-19,21-24,51 and 52*.

3. ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
   a) ☐ All b) ☐ Some* c) ☐ None of the:
      1. ☐ Certified copies of the priority documents have been received.
      2. ☐ Certified copies of the priority documents have been received in Application No. _____ .
      3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

   * Certified copies not received: _____.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.
THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.

4. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.

5. ☐ CORRECTED DRAWINGS (as "replacement sheets") must be submitted.
   (a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review (PTO-948) attached
      1) ☐ hereto or 2) ☐ to Paper No./Mail Date _____.
   (b) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date _____.

   Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).

6. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

Attachment(s)

1. ☐ Notice of References Cited (PTO-892)
2. ☐ Notice of Draftperson's Patent Drawing Review (PTO-948)
3. ☐ Information Disclosure Statements (PTO/SB/08), Paper No./Mail Date _____
4. ☐ Examiner's Comment Regarding Requirement for Deposit of Biological Material
5. ☐ Notice of Informal Patent Application
6. ☒ Interview Summary (PTO-413), Paper No./Mail Date *12/20/07;01/07/08* .
7. ☒ Examiner's Amendment/Comment
8. ☐ Examiner's Statement of Reasons for Allowance
9. ☐ Other _____.

SANDRA E. SAUCIER
PRIMARY EXAMINER

EXAMINER'S AMENDMENT

An examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it MUST be submitted no later than the payment of the issue fee.

Authorization for this examiner's amendment was given in a telephone interview with Applicant's Attorney, Ingrid Beattie, on January 7, 2008.

The application has been amended as follows:

The Specification has been amended as follows:

The first paragraph of the specification has been amended to recite:

"This Application is a national stage Application filed under 371 based on PCT/US98/11347 filed June 3, 1998, which claims priority to provisional Application 60/048,452, filed June 3, 1997."

The phrase "lactid acid bacterium" (page 19, ¶3, line 11) has been amended to correct a typographical error. The phrase has been amended to recite "lactic acid bacterium".

Claims:

1. A method of reducing a bacterial gastrointestinal infection in a human, said bacterial gastrointestinal infection selected from the group consisting of *Clostridium perfringens, Clostridium difficile, Clostridium botulinum, Clostridium tributrycum, Clostridium sporogenes, Escherichia coli, Pseudomonas aeruginosa, and Staphylococcus aureus*, comprising the steps of:

a) orally administering to a human subject in need thereof a composition comprising:

i.) viable colony forming units (CFU) of a non-pathogenic lactic acid bacteria, wherein said non-pathogenic lactic acid bacteria is *Bacillus coagulans;* and

ii) an oral electrolyte maintenance formulation; and

b) allowing said non-pathogenic lactic acid bacteria to grow in the human subject's gastrointestinal tract, thereby reducing a bacterial gastrointestinal infection.

2. The method of Claim 1, wherein the human subject is an infant at risk for Sudden Infant Death Syndrome (SIDS).

3. (Canceled)

4. The method of claim 1, wherein the non-pathogenic lactic acid bacteria is included in the composition in the form of spores.

5. The method composition of claim 1, wherein the non-pathogenic lactic acid bacteria is included in the composition in the form of a dried cell mass.

6. The method of claim 1, wherein the non-pathogenic lactic acid bacteria is in the form of spores, and said method further comprises allowing the spores to germinate after the administering step.

7. The method of claim 1, wherein said composition contains 10^3 to 10^{12} CFU of viable non-pathogenic lactic acid bacteria or spores per gram of composition.

8. The method of claim 1, wherein said administering comprises introducing into the digestive tract from 0.1 to 50 grams per day of the non-pathogenic lactic acid bacteria in step (a)(i).

9. The method of claim 1, wherein said administering comprises introducing into the digestive tract from 10^2 to 10^{10} viable bacteria or spores per day.

10. The method of claim 9, wherein said administering comprises introducing into the digestive tract from 10^3 to 10^6 viable bacteria or spores per day.

11. The method of claim 9, wherein said administering comprises introducing into the digestive tract from 10^6 to 10^9 viable bacteria or spores per day.

12. The method of claim 1, wherein said composition in step (a) further comprises an effective amount of a bifidogenic oligosaccharide to promote the growth of the non-pathogenic lactic acid bacteria.

13. The method of claim 12, wherein the bifidogenic oligosaccharide is selected from the group consisting of fructo-oligosaccharide (FOS), gluco-oligosaccharide (GOS), raffinose, and long-chain oligosaccharides.

14. The method of claim 13, wherein the bifidogenic oligosaccharide comprises a polysaccharide having a polymer chain length of about 4 to 100 sugar units.

15. The method of claim 1, wherein the composition further comprises about 10 milligrams to about 1 gram of FOS per gram of composition.

16. The method of claim 1, wherein the composition further comprises from 100 to 500 milligrams of FOS per gram of composition.

17. The method of claim 1, wherein the administering comprises introducing into the digestive tract from 10 milligrams to 20 grams of fructo-oligosaccharide per day.

18. The method of claim 1, wherein the administering comprises introducing into the digestive tract from 150 milligrams to 5 grams of fructo-oligosaccharide per day.

19. The method of claim 1, wherein the composition in step (a) further comprises a food substance, flavoring, vitamin or mineral.

20. (Canceled)

21. The method of claim 1 wherein the oral electrolyte maintenance formulation in step (a)(ii) is a powder comprising sodium chloride, potassium citrate, citric acid, or glucose.

22. The method of claim 1 wherein the oral electrolyte maintenance formulation in step (a)(ii) is rehydrated with water to produce a solution comprising 45 to 75 mEq/1 of sodium, 20 mEq/1 of potassium, 35 to 65 mEq/1 of chloride, 30 mEq/1 of citrate, 20-25 g/1 of glucose, and wherein said non-pathogenic lactic acid bacteria in step (a)(i) comprises about 5×10^5 to about 5×10^7 viable CFU of said bacteria/1.

23. The method of claim 1, wherein the composition in step (a) further comprises an extracellular product of *Bacillus coagulans*.

24. The method of claim 23, wherein the extracellular product is a supernatant or filtrate of a culture of an isolated *Bacillus coagulans* strain.

25-50. (Canceled)

51. The method of claim 1, wherein the non-pathogenic lactic acid bacteria comprises *Bacillus coagulans* hammer strain Accession No. ATCC 31284.

52. The method of claim 1, wherein the oral electrolyte maintenance formulation in step (a)(ii) comprises 45 to 75 mEq/1 of sodium, 20 mEq/1 of potassium, 35 to 65 mEq/1 of chloride, 30 mEq/1 of citrate, and 20 to 25 g/1 of glucose.

53. (Canceled)

Miscellaneous (Note Regarding Deposited Microorganisms)

It is noted that the microorganism(s) required to practice the claimed invention is/are currently available from repository (ATCC). It appears that this/these microorganism(s) should

remain available to the public beyond the effective life of the patent. Any information to the contrary which comes to an applicant's attention *during the prosecution of this application,* must be entered in the record or otherwise be brought to the attention of the Office by the applicant.

If an Applicant has adequately established that a biological material is known and readily available, the Office will accept that showing. In those instances, however, the Applicant takes the risk that the material may cease to be known and readily available. Such a defect cannot be cured by reissue after the grant of a patent. ***(MPEP 2404.01;* see 37 CFR 1.801- 37 CFR 1.809).**

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Aaron J. Kosar whose telephone number is (571) 270-3054. The examiner can normally be reached on Monday-Thursday, 7:30AM-5:00PM, ALT. Friday,EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mike Wityshyn can be reached on (571) 272-0926. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/ak/
Aaron Kosar
Examiner, Art Unit 1651

SANDRA E. SAUCIER
PRIMARY EXAMINER